

No. 75-1540

Supreme Court, U. S.

FILED

JUN 23 1976

MICHAEL RODAK, JR., CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1975

NATICK PAPERBOARD CORP., ET AL., PETITIONERS

v.

**F. DAVID MATHEWS, SECRETARY OF HEALTH, EDUCATION
AND WELFARE, ET AL.**

**ON PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS FOR
THE FIRST CIRCUIT**

BRIEF FOR THE RESPONDENTS IN OPPOSITION

ROBERT H. BORK,
Solicitor General,

THOMAS E. KAUPER,
Assistant Attorney General,

**BARRY GROSSMAN,
EDWARD E. LAWSON,**
*Attorneys,
Department of Justice,
Washington, D.C. 20530.*

RICHARD A. MERRILL,
*Chief Counsel,
Food and Drug Administration,
Rockville, Maryland 20852.*

In the Supreme Court of the United States

OCTOBER TERM, 1975

No. 75-1540

NATICK PAPERBOARD CORP., ET AL., PETITIONERS

v.

F. DAVID MATHEWS, SECRETARY OF HEALTH, EDUCATION
AND WELFARE, ET AL.

*ON PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS FOR
THE FIRST CIRCUIT*

BRIEF FOR THE RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-9a) is reported at 525 F. 2d 1103. The opinion of the district court (Pet. App. 10a-15a) is reported at 389 F. Supp. 794.

JURISDICTION

The judgment of the court of appeals was entered on November 26, 1975. On February 17, 1976, Mr. Justice Brennan extended petitioners' time within which to petition for a writ of certiorari to April 23, 1976, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether the Food and Drug Administration has the authority to recommend seizure of food-packaging

material containing excessive amounts of a toxic chemical when such chemical combines with and adulterates food packaged in the material.

STATUTORY PROVISIONS INVOLVED

Pertinent provisions of the Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1040, as amended, 21 U.S.C. 321 *et seq.*, are set forth at Pet. 2-3.

STATEMENT

Respondents, the Secretary of Health, Education and Welfare and the Commissioner of Food and Drugs ("FDA"), have determined that polychlorinated biphenyls (PCB's) are toxic chemicals that should not be present above a specified level in foods. On July 6, 1973, the FDA published a proposed regulation designed to limit the occurrence of PCB's in food. A provision of the regulation would prohibit PCB residues of more than ten parts per million in paper food packaging material unless such material is separated from the food contained therein by a functional barrier impermeable to the migration of PCB's.¹ This proposed regulation, which is not challenged here (Pet. 4, n. 1), has not yet become effective. On August 24, 1973, however, the FDA announced (38 Fed. Reg. 22794) that all paper food-packaging material containing PCB's in excess of the announced standard would be considered an adulterated food and thus subject to seizure (Pet. App. 2a-3a).

Petitioners, Natick Paperboard Corporation and Crown Paperboard Company, Inc., manufacture paper packaging material, some of which is used for food packaging.

¹21 C.F.R. 122.10(a)(9).

Certain types of waste paper used by Natick in the manufacture of the packaging material contain PCB's. Petitioners sought a declaratory judgment² that FDA's August 24, 1973, notice was promulgated without statutory authority, because food packaging material could not be classified as a "food" subject to the seizure provisions of 21 U.S.C. 334(a)(1).

The district court granted respondents' motion for summary judgment. It held that food-packaging that may become a component or otherwise affect the characteristics of any food is a "food additive" as defined in 21 U.S.C. 321(s) (Pet. App. 12a-13a). Under 21 U.S.C. 342(a)(2)(C), a food is adulterated if it is, bears or contains any unsafe food additive. Food packaging containing excessive levels of PCB's may thus constitute an adulterated food subject to seizure. This application of the statute, the district court held, was consistent with the general congressional purpose, reflected in the legislative history, "to monitor and regulate anything traveling in interstate commerce which ultimately would be ingested by human beings, regardless of the label appended thereto" (Pet. App. 13a-15a).

The court of appeals unanimously affirmed (Pet. App. 1a-9a). It found that there was sufficient evidence to justify the district court's finding that food-packaging material containing PCB's in excess of 10 ppm is an "unsafe food additive" as defined in 21 U.S.C. 321(s).

²Petitioners initially sought both declaratory and injunctive relief, but the district court denied all relief on the basis that it lacked jurisdiction. 367 F. Supp. 885 (D. Mass.). The court of appeals affirmed the district court with respect to the injunction, but reversed and remanded the case for the district court to adjudicate the merits of the request for declaratory relief. 498 F. 2d 125 (C.A. 1).

348(a) (Pet. App. 4a-5a). It noted that in the Food Additives Amendment of 1958 (72 Stat. 1784), Congress expanded the definition of "adulterated food" to include any component of food that is an "unsafe food additive" (Pet. App. 5a-7a). Relying upon the Amendment's history, the court rejected petitioners' assertion that only those "unsafe food additives" that were intended to be mixed with foods could be considered "foods" within the meaning of the Act. Rather, it was sufficient if the intermixture resulted from the intended use of the additive (Pet. App. 7a, nn. 8 and 9). The court reasoned that limiting the seizure provisions of the Act to cases of intentional mixing of unsafe food additives and foods, or requiring the FDA to delay seizure until after contamination actually occurred,* would be inconsistent with the statutory policy of protecting public health and safety (Pet. App. 8a). The court held, however, that the FDA may seize only paperboard containing excessive PCB's which is clearly intended for use as food packaging, and if the food is protected by a barrier impenetrable to PCB's, the food is not subject to seizure. So construed, the court held FDA's notice of seizure is not overbroad.

ARGUMENT

The decision of the court of appeals is correct and there is no reason for this Court to grant the petition.

1. Petitioners appear to concede (Pet. 7) that their food packaging material is a food additive under 21 U.S.C. 321(s). Nevertheless, they contend it may not be deemed an adulterated food subject to the seizure provisions of the Act because it is not intended to become intermixed as a component of food. That contention is contrary to the language of the statute, which treats an unsafe "food additive" as an adulterated "food," without regard to intended intermixture.

Section 321(s) declares that "'food additive' means any substance the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, (including any substance intended for use in *** packaging *** or holding food ***)" if it is not generally recognized by qualified experts to be safe "under the conditions of its intended use." And 21 U.S.C. 342(a)(2)(C) provides that "[a] food shall be deemed to be adulterated *** if it is *** any food additive which is unsafe within the meaning of Section 348 of this Title ***." For the purpose of this case, petitioners have not questioned FDA's findings that PCB's migrate from the packaging material to the packaged food, and that paper packaging materials are unsafe food additives when PCB residues in excess of 10 ppm are contained therein, 21 C.F.R. 122.10(a)(9) (Pet. 4, n. 1). Therefore, under 21 U.S.C. 342(a)(2)(c), food packaging material containing PCB residues in excess of 10 ppm is an adulterated food subject to seizure under 21 U.S.C. 334.

This conclusion is supported by the 1958 Amendment's legislative history. The House Subcommittee rejected a proposal to include "food additives" within the definition of food because the Act already defined "food" to include all components thereof (104 Cong. Rec. 17418 (1958)) (Pet. App. 13a). Congress assumed that when packaging material contains a substance which intermixes with food contained within it, it thereby becomes a component of, or affects, the food, and should therefore be treated like a food within the meaning of 21 U.S.C. 321(s), whether or not the intermixture was intended. See H.R. Rep. No. 2284, 85th Cong., 2d Sess. 3 (1958); S. Rep. No. 2422, 85th Cong., 2d Sess. 4, 5 (1958) (Pet. App. 7a, n. 9).

Petitioners not only fail to cite any contrary legislative history, but also fail to identify any policy that would support the distinction they seek to draw. From the perspective of protecting the public health and safety, it makes no difference whether the manufacturer intended an unsafe additive to intermix with a food, or whether the intermixture was unintended but was nevertheless an occurrence reasonably to be expected. In rejecting petitioners' argument that the relevant provisions of the Act turn upon whether the critical intermixture was intended, as distinguished from reasonably to be expected, the lower courts were correct in looking to the general purpose of the statute to corroborate their analysis of the statutory language and legislative history. As this Court stated in *United States v. Dotterweich*, 320 U.S. 277, 280, proper regard for the Act's purpose to protect life and health "should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely a collection of English words." See also *United States v. An Article of Drug * * * Bacto-Unidisk*, 394 U.S. 784, 798; *United States v. Sullivan*, 332 U.S. 689, 696-697.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

ROBERT H. BORK,
Solicitor General.

THOMAS E. KAUPER,
Assistant Attorney General.

BARRY GROSSMAN,
EDWARD E. LAWSON,
Attorneys.

RICHARD A. MERRILL,
Chief Counsel,
Food and Drug Administration.

JUNE 1976.